PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PAC/22974 WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/GB2004/002731	International filing date *(day/month/year)* 24.06.2004	Priority date *(day/month/year)* 24.06.2003
International Patent Classification (IPC) or national classification and IPC B65D83/14, A61M15/00		
Applicant CIPLA LIMITED et all.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.02.2005	09.09.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Mans-Kamerbeek, M Telephone No. +31 70 340-3969

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/002731

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-9 as originally filed

Claims, Numbers

1-11 filed with telefax on 22.04.2005

Drawings, Sheets

1/1 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 12-15
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	11
Inventive step (IS)	Yes:	Claims	1-10
	No:	Claims	11
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: GB-A-2 195 544 (UNIVERSAL PRECISION MOULDERS L) 13 April 1988 (1988-04-13)

D2: US-A-3 746 196 (SAKO E ET AL) 17 July 1973 (1973-07-17)

1)

Document D1, which is considered to represent the most relevant state of the art, discloses a metered dose inhaler from which the subject-matter of claim 1 differs in that the canister is made of polycarbonate without any coating on the interior surface thereof.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as preventing the formulation from adhering to the inner wall of the canister.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

none of the prior art discloses the use of polycarbonate in canisters for MDI's to prevent adherence of the formula to the inner walls of the canister. Even though D2 discloses the use of a polycarbonate container, this document would not lead the skilled man to the solution as proposed in claim 1, simply because the document does not refer to any anti-adherent properties and would therefore not be considered. Besides that, the container of D2 is not a canister for an MDI.

2)

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 9 and 10, which therefore are also considered new and inventive.

3)
The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 11 is not new in the sense of Article 33(2) PCT.

The document D2 discloses the use of polycarbonate in a pharmaceutical dispenser and therefore automatically performs the functions of providing transparency and reducing adhesion of the formulation to the inner wall of the dispenser.

4)
Claims 2-8 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Claims

1. A metered dose inhaler comprising a canister and a metering valve attached to the canister, wherein the canister is sufficiently transparent that a formulation disposed within the canister is visible from the exterior of the canister, and wherein the canister is polycarbonate and does not have any coating on the interior surface thereof..

2. A metered dose inhaler according to claim 1, wherein the canister is entirely transparent.

3. A metered dose inhaler according to claim 1 or 2, wherein the canister is provided with markings indicative of the number of doses of formulation remaining in the canister.

4. A metered dose inhaler according to any preceding claim, further comprising a formulation containing an active pharmaceutical substance selected from the group of bronchodilators, long acting bronchodilators, beta-2-adrenoceptors, anticholinergics, steroids, beta-2-agonists and antiallergics.

5. A metered dose inhaler according to claim 4, wherein the active pharmaceutical substance is salbutamol, ipratropium or budesonide.

6. A metered dose inhaler according to claim 4 or 5, wherein the formulation further comprises a propellant.

7. A metered dose inhaler according to any preceding claim, further comprising an actuator for actuating the metering valve.

8. A metered dose inhaler according to claim 7, wherein the actuator is configured such that, in use, it does not prevent the user from seeing the level of formulation in the canister.

9. A method of making a metered dose inhaler according to any preceding claim,

comprising forming a polycarbonate canister by injection molding or injection blow molding, placing a pharmaceutical formulation in the canister, then securing a metering valve to the canister.

10. The use of polycarbonate in a canister of a metered dose inhaler to perform the dual functions of: providing sufficient transparency of the canister that a user can see the amount of formulation present within the interior of the canister; and reducing or preventing the adhesion of the formulation to the interior surface of the canister.

11. The use of polycarbonate in a pharmaceutical dispenser to perform the dual functions of: providing sufficient transparency of the dispenser that a user can see the amount of formulation present within the interior of the dispenser; and reducing or preventing the adhesion of the formulation to the interior surface of the dispenser.